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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,368	10/26/2001	James P. Hoffler	INVIT1100-2	2504

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GRAY CARY WARE & FREIDENRICH LLP
4365 EXECUTIVE DRIVE
SUITE 1100
SAN DIEGO, CA 92121-2133

EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,368	HOEFFLER ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,20-24 and 48-70* is/are pending in the application.

4a) Of the above claim(s) *20,51-54 and 56-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,21-24,48-50,55 and 60-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03262004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/26/04 has been entered.

Amendment Entry

2. Applicants' response to the office action mailed 24 September 2003 is acknowledged. In the amendment filed therein claim 18 and the specification were modified. Currently claims 18, 21-24, 48-50, 55, and 60-70 are under consideration.

OBJECTIONS

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the Examiner on form PTO-892 or Applicant on form PTO-1449 has cited the references they have not been considered.

4. The information disclosure statements (IDS) filed 26 March 2004 has been considered as to the merits before Final Action.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 18, 48, and 49 are rejected under 35 U.S.C. 103(a) as being obvious over Baecher-Allan et al. (Immunogenetics, 1993, 37/3, 183-192) in view of Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991).

Baecher-Allan et al. disclose methods to screen uncharacterized or unknown antibodies. Specifically the 3E8-specific monoclonal antibody (mAb) and the S7 mAb both recognize the sialoglycoprotein Ly-48. The binding expression or patterns of the two known monoclonal antibodies (3E8 and S7) were compared with two uncharacterized antibodies S11 and S15. See abstract.

All four antibodies were exposed to different cell lysates of cell populations K562.LY48, K562.B-Actin, EL-4, Line1.β-Actin, Line1.Ly48.3, and Line1.Ly48.6. See page 188.

Baecher-Allan et al. differ from the instant invention in not specifically teaching an array configuration including the antibody compositions.

However, Ekins et al. teach method to detect proteins via multianalyte microspot immunoassays. An array of antibodies (device comprising multiple immobilized agents for protein detection such as antibodies) is exposed to proteins to monitor the expression and properties of a large number of proteins. See abstract and figures 4 and 5.

The detection procedure can be evaluated with a radioactive isotopes (i.e. I125), an enzyme, chemiluminescent label, or fluorescence label. See page 1960. In one embodiment dual microspot assay devices are compared. See page 1961 figure 8 for example.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the high through put protein patterning procedure/microspots of Ekins et al. in the antibody screening methods of Baecher-Allan because Ekins et al. taught that his microspot procedure allowed for highly sensitive immunoassays with smaller amounts of antibody as well as the simultaneous measurement of thousands of different substances. See page 1965 2nd column 3rd paragraph through page 1966 1st column 1st paragraph.

II. Claims 21, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baecher-Allan et al. (Immunogenetics, 1993, 37/3, 183-192) in view of Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) as applied to claims 18, 48, and 49 above, and further in view of Yates, III et al. (5,538,897).

Please see Baecher-Allan et al. in view of Ekins et al. as set forth above.

Baecher-Allan et al. in view of Ekins et al. differ from the instant invention in not specifically teaching the generation of binding patterns for differential state or disease comparison.

However Yates et al. disclose the evaluation of binding patterns to identify peptide amino acid sequences. See abstract. Antibody-protein binding is employed to measure cellular proteins (resting state –normal state). The protein pattern or fragment is stored and compared with database patterns to determine diseases and/or disorders (stimulated state).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use protein patterning procedures as taught by Yates,III et al. in the method of Baecher-Allan et al. in view of the high through put protein pattering procedure/microspots of Ekins et al. because Yates, III et al. taught that binding patterns could not only identify disease and or disorders but could further identify the sequence or sub-sequences of the proteins/peptides involved. See column 2 lines 1-19.

III. Claims 22, 50, 60-63, 69, and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baecher-Allan et al. (Immunogenetics, 1993, 37/3, 183-192) in view of Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) and further in view of Yates, III et al. (5,538,897) and James F. Cupo (Journal of Chromatography, 569, 1991, 389-40).

Please see Baecher-Allan et al. (Immunogenetics, 1993, 37/3, 183-192) in view of Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) and further in view of Yates, III et al. (5,538,897) as set forth above.

Baecher-Allan et al. (Immunogenetics, 1993, 37/3, 183-192) in view of Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) and further in view of Yates, III et al. (5,538,897) differ from the instant invention in not teaching protein expression pattern evaluation in cancer diseases or virus cell lines (like T cells) and further allowing for cellular replication distinctions (differential development) via polyacrylamide.

However, Cupo teaches a two-dimensional polyacrylamide gel electrophoresis procedure to measure matrix proteins. The proteins are tissue-type specific and can reflect changes in the state of differentiation of a cell. The method can further distinguish between a diseased cell and a normal cell. The disease states include various cancers, autoimmune disease, and adenoviral infection. See abstract. The method is quick and efficient employing the appropriate antibodies to the protein of interest. Page 403, 1st paragraph. Protein patterning in T lymphocytes (T cells) is outlined on page 400. The method is used to detect early stages of viral infection because a virus must replicate cellular components associated with the nuclear matrix. Such changes are evident in protein patterning analysis. See page 403 – 4.3.

With respect to the solid phase possibilities listed in claims 60-62, it is noted that various solid phase compositions are taught in the prior art. Absent evidence to the contrary the selection of any one of the known solid phase surfaces is routine adjustment of the solid phase methods exhibited by the cited prior art.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use protein patterning procedures to evaluate cancer diseases or virus cell lines (like T cells) and further allowing for cellular replication distinctions (differential development) via polyacrylamide as taught by Cupo in the high through put protein pattering procedure of Baecher-Allan et al. (Immunogenetics, 1993, 37/3, 183-192) in view of Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) and further in view of Yates, III et al. (5,538,897) because Cupo taught that two-dimensional gels can determine tissue-type specific differences in nuclear matrix proteins and the differences between normal and carcinogenic cells. See page 402 - 4.2

Further these proteins play an important role in cells. Utilization of the proteins can lead to the development of diagnostic agents to detect various diseased conditions of the cell and organism (including cancer and viruses). Cupo page 404.

IV. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baecher-Allan et al. (Immunogenetics, 1993, 37/3, 183-192) in view of Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) and further in view of Yates, III et al. (5,538,897) and James F. Cupo (Journal of Chromatography, 569, 1991, 389-40).

Please see Baecher-Allan et al. (Immunogenetics, 1993, 37/3, 183-192) in view of Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) in view of Yates, III et al. (5,538,897) and in further view of Cupo as set forth above.

Baecher-Allan et al. (Immunogenetics, 1993, 37/3, 183-192) in view of Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) in view of Yates, III et al. (5,538,897) and in further view of Cupo differ from the instant invention in not specifically teaching the first cell lysate comprising an arterial endothelial cell lysate and the second cell lysate comprising a venous endothelial cell lysate.

However such modification with respect to the type of cells evaluated in the instant method is view as mere design choice and optimization. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to various cells in the methods of Chin et al. in view of Cupo because it would have been an obvious combination of a known cells to evaluate their protein expression via the methods taught by Chin et al. in view of Cupo. The changes in cell type for evaluation are routine optimizations that are almost always determined and used in methods to test the properties of interest.

Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been prima facie obvious for one of ordinary skill in the art to analyze various cell types\ in the given parameters to determine the unknown as a means of optimizing the methods provided by the art.

V. Claim 55 and 64-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baecher-Allan et al. (Immunogenetics, 1993, 37/3, 183-192) in view of Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) and further in view of Kauvar (US Patent #5,541,070).

Please see Baecher-Allan et al. (Immunogenetics, 1993, 37/3, 183-192) in view of Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) as set forth above.

Baecher-Allan et al. (Immunogenetics, 1993, 37/3, 183-192) in view of Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) differ from the instant invention in not teaching immunoglobulin (Ig) antibody binding affinity.

Kauvar teach method of characterizing drugs (proteins) via antibody arrays comprising different binding affinities. The antibody arrays produce characteristic profiles (protein profiles), which can be evaluated or compared to assess the analyte in compound detected. See abstract and figure 5. The antibodies used were mostly of the IgG, IgM forms with vary binding affinity (binding coefficients). See column 8 line 11-14 and figure 2B.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to employ various immunoglobulin antibodies with various affinities as taught by Kauvar in the methods of Ekins et al. (Clin Chem. 37/11, 1955-1967, 1991) in view of Yates, III et al. (5,538,897) because Kauvar taught that his invention offered a method of profiling a particular analyte by taking advantage of its specific pattern of reactivity against a panel of antibodies of varying specificity and affinity. Column 3 lines 11-24.

In this method small quantities of analyte can be tested against a large collection of potentially cross reactive antibodies to generate rapid, low cost, data analysis. Column 4 lines 60-67.

8. For reasons aforementioned, no claims are allowed.

Remarks

9. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

Kingsmore et al. (U.S. Patent#6,531,283) teach protein expression profiling techniques.

Fields et al. (U.S. Patent #5,283,173) disclosed systems to measure protein-protein interactions.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 872-9306, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Lisa V. Cook
Patent Examiner
Art Unit 1641
3C-59
(571)272-0816
6/22/04

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
06/25/04